Formulation and Evaluation of Orodispersible Tablet of Sulindac

Bhavna B. Gaikwad, Bhushan R. Rane, and Ashish S. Jain

ABSTRACT

Oral administration of dosage form is the most recommended mode of administration, because of its self-medication, accurate dose of the drug, and ease of administration. However, trouble swallowing in geriatric patients is one major negative of this route, which can mentally disrupt patients. The goal of this study was to use the direct compression method to make orodispensible tablets of sulindac utilizing various doses of super disintegrant agents such as Sodium starch glycolate Crospovidone and Croscarmellose sodium. Three distinct super disintegrants were used to create nine formulations with varying concentration levels. The preformulation, precompression, and post-compression properties of the powder combinations were assessed. In comparison to the other formulations, tablets from batch F3 containing crospovidone had superior organoleptic qualities, as well as outstanding drug release and in-vitro disintegration time. The super disintegrants addition technique was shown to be a viable method for manufacturing orodispersible tablets using the direct compression method.

Keywords: Croscarmellose sodium, crospovidone, direct compression method, orodispensible tablets (ODTs), sodium starch glycolate, sulindac.

I. INTRODUCTION

Oral medication is the most common form of drug administration because of advantages such as convenience of drug administration via the oral route, patient preference, cost-effectiveness, and ease of large-scale manufacturing of oral dosage forms. Around 60% of established small-molecule drug products available commercially are administered via the oral route. The compliance of patients to oral formulations is generally higher than that to other parenteral routes such as intravenous, subcutaneous, and intramuscular injections, as well as to inhalation for asthma medications. Sulindac is an aryalkanoic acid-class nonsteroidal anti-inflammatory medication (NSAID) marketed by Merck under the brand name Clinoril. It can be used to treat acute or chronic inflammatory disorders, just as other NSAIDs. Sulindac is a sulfonilindene-derived prodrug that is transformed into an active sulfide molecule by liver enzymes in vivo. The specific mechanism of action of Sulindac is unclear. Its anti-inflammatory properties are thought to be due to the inhibition of COX-1 and COX-2, which inhibits prostaglandin formation. Hypothalamic stimulation, which promotes increased peripheral blood flow, vasodilation, and heat dissipation, could be linked to antipyretic effects [1]. When placed on the tongue, orodispensible tablets instantly disintegrate, releasing the medicine, which dissolves or disperses in the saliva [2]. It is difficult to swallow hard gelatin capsules and tablets for some patients, and as a result, they do not follow their prescriptions, resulting in a high rate of non-compliance and inefficient treatment [3]. As a new medicine delivery technology, orodispensible tablets are gaining popularity [4]. The faster the medicine dissolves in the fluid, the faster it is absorbed and the therapeutic action begins. As saliva goes down into the stomach, some drugs are absorbed from the mouth, throat, and esophagus. In such circumstances, a drug's bioavailability is much higher than that observed with traditional tablet dose forms. Industry and academics are rapidly recognizing the benefits of orodispensible dosage forms. Their expanding relevance was recently highlighted by the adoption of the term "Orodispensible Tablet" by the European Pharmacopoeia, which refers to a tablet that is placed in the mouth and disperses fast before being swallowed [5]. Without the use of water or chewing, these dosage forms disintegrate and dissolve in the oral cavity within a minute [6]. Though traditional oral tablets are commonly used, they have a few practical limitations, such as their inability to provide a rapid beginning of the action. When dealing with mentally ill and uncooperative patients, traditional oral dose forms might be inconvenient. Due to a lack of water, it can be difficult to swallow conventional items at times [7], [8]. As a result, the goal of this study was to use crospovidone, sodium starch glycolate, and croscarmellose sodium as super disintegrants in the formulation of sulindac orodispensible tablets. Our work shows rapid drug delivery together with the need for easy-to-swallow oral drugs in certain patient populations (including pediatric and geriatric patients) has triggered an important trend towards orodispensible tablets. One principal goal of oral drug administration is to ensure high and reliable bioavailability of the drug.
II. MATERIALS AND METHODS

A. Materials

Sulindac is obtained from TCI Development Co., Ltd., crospovidone, magnesium stearate, talc, croscarmellose sodium, mannitol, sodium starch glycolate, saccharin and vanilla.

B. Methods

1) Preparation of Sulindac - Orodispersible Tablets

The Direct Compression Method was used to make the Orodispersible tablets. Appropriate quantities of Sulindac (150 mg) and super disintegrants like Sodium starch glycolate, Croscarmellose sodium, Crospovidone and other excipients were measured accurately as shown in the Table 1. All the measured powders were passed through sieve number 60. The powder blend was mixed by mortar-pestle and compressed into a tablet by Kambert Multi-Station tablet compression machine by using 8 mm punch. The total weight of the tablet is 200 mg.

III. EXPERIMENTAL

A. Preformulation Studies

1) Organoleptic Properties

The appearance and Colour of the pure drug were checked by visual inspection and noted as observations.

2) Physicochemical Properties

a) Determination of Solubility [9]

Solubility test of the drug is performed to confirm its purity by saturation method and measured using UV-Visible Double beam spectrophotometer.

b) Melting Point Determination [10]

Sulindac's melting point was established using Thiele's tube method. Heating was used to seal one end of the capillary tube. The drug powder was then placed inside the capillary tube, which was then threaded with the thermometer and placed inside Thiele's tube containing liquid paraffin. The heating was then turned on, and the temperature was gradually raised. When the medication had melted, the temperature was recorded.

3) Estimation of $\lambda_{\text{max}}$ and Development of Standard Calibration Curve Method by UV Visible Spectrophotometer [10]

a) Preparation of Standard Calibration Curve of Sulindac in Ethanol

Preparation of working standard stock solution

The drug was weighed and dissolved in Ethanol to obtain a concentration of 100 ppm. This solution was used as a standard stock solution to obtain further dilutions.

- Spectrophotometric scanning of Sulindac
  - From the stock solution, the UV scan was performed between the wavelength range of 200-400nm and the highest peak in the spectra was selected as the maximum wavelength for Sulindac.
  - Preparation of standard plot of Sulindac in Ethanol
    - From the standard stock solution of Sulindac, dilutions of 10, 20, 30, 40 and 50 ppm were prepared and the absorbance was measured by using UV Visible double beam spectrophotometer.

b) Preparation of Standard Calibration Curve of Sulindac in Phosphate Buffer Solution (pH 7.2)

- Preparation of standard stock solution
  - To obtain a concentration of 100ppm, the drug was weighed and dissolved in a phosphate buffer solution with a pH of 7.2. To obtain further dilutions, this solution was utilized as a standard stock solution.
  - Spectrophotometric scanning of Sulindac
    - From the stock solution, the UV scan was performed between the wavelength range of 200-400nm and the highest peak in the spectra was selected as the maximum wavelength for Sulindac.
  - Preparation of standard plot of Sulindac in Phosphate buffer solution:
    - From the standard stock solution of sulindac, dilutions of 10, 20, 30, 40 and 50 ppm were prepared and the absorbance was measured by using a UV visible double beam spectrophotometer.

4) FTIR Studies [10]

a) Confirmation of Drug by FTIR

Sulindac was subjected to a qualitative IR analysis utilizing the Shimadzu IR Affinity-1S. The drug was ground and thoroughly mixed with potassium bromide, then compressed under 5 tonnes of pressure for 5 minutes using a hydraulic press to make the KBr disc. Scans were taken at a resolution of 4 cm$^{-1}$ from 4000 to 400 cm$^{-1}$. The spectrum was confirmed by comparing it to Sulindac's IR spectra.

5) Drug-Excipients Study by FTIR

The IR spectrum of API, Excipients and drug-excipients mixture were recorded by FTIR. The compatibility of drug and excipients was checked by comparing different spectrums obtained by FTIR studies.

B. Design of ODT Formulations

Formulation of Sulindac Orodispersible tablet by 9 formulations. From this, an optimized formulation will be selected.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Ingredients</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Sulindac</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>2.</td>
<td>Crospovidone</td>
<td>5</td>
<td>10</td>
<td>12.5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3.</td>
<td>Sodium starch glycolate</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>4.</td>
<td>Croscarmellose sodium</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>5</td>
<td>10</td>
<td>12.5</td>
</tr>
<tr>
<td>5.</td>
<td>Magnesium stearate</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>6.</td>
<td>Talc</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>7.</td>
<td>Saccharin</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>9.</td>
<td>Vanilla</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
<td>1.875</td>
</tr>
</tbody>
</table>

All quantity is in mg
C. Precompression Evaluation Studies [8],[11]-[13]

1) Bulk Density

Powders were accurately weighed and lightly shook to break up any agglomerates before being placed in a 25 ml measuring cylinder. Without disturbing the cylinder, the amount of space occupied by the powder was calculated, and the bulk density was determined using the equation,

\[ \text{Bulk Design (BD)} = \frac{\text{Weight of powder}}{\text{Volume covered by the powder}} \] (1)

2) Tapped Density

Powders were accurately weighed and lightly shook to break up any agglomerates before being placed in a 25 ml measuring cylinder. Using the Digital Bulk Density Apparatus, a standard technique was followed to calculate tapped density. The final volume was recorded, and the equation was used to compute the tapped density.

\[ \text{Tapped Density (TD)} = \frac{\text{Weight of powder}}{\text{Volume occupied by the powder}} \] (2)

3) Carr’s Index

Carr’s index is a measurement of a powder’s capacity to shrink in volume under pressure. It is widely used to describe the flowability of a substance. A Carr’s index of 5-15 percent is considered excellent, and acceptable up to 21%, while a Carr’s index of more than 23% indicates inadequate flow. The below formula is used to calculate it,

\[ \text{Carr’s Index (I)} = \frac{\text{Bulk Design (BD)} - \text{Tapped Density (TD)}}{\text{Tapped Density (TD)}} \times 100 \] (3)

4) Hausner’s Index

Hausner's ratio is a measurement of powder flowability. If Hausner's ratio is less than 1.25, the flow is good. It's calculated using the formula below,

\[ \text{Hausner’s Ratio} = \frac{\text{Tapped Density (TD)}}{\text{Bulk Design (BD)}} \] (4)

5) Angle of Repose

The angle of repose of powder mixtures was determined using the funnel method. A total of three determinations were made. The equation was used to determine the angle of repose.

\[ \text{Angle of Repose (θ)} = \tan^{-1} \frac{h}{r} \] (5)

Where, h is the height of the pile; r is the radius of the base pile.

\[ \begin{array}{|c|c|c|}
\hline
\text{Sr. No.} & \text{Carr’s Index} & \text{Flowability} \\
\hline
1. & 5 - 15 & Excellent \\
2. & 12 - 16 & Good \\
3. & 18 - 21 & Fair-passable \\
4. & 23 - 35 & Poor \\
5. & 33 - 38 & Very poor \\
6. & > 40 & Very, very poor \\
\hline
\end{array} \]

\[ \begin{array}{|c|c|c|}
\hline
\text{Sr. No.} & \text{Hausner’s Ratio} & \text{Flowability} \\
\hline
1. & 1.05 - 1.18 & Excellent \\
2. & 1.14 - 1.20 & Good \\
3. & 1.22 - 1.26 & Fair-passable \\
4. & 1.30 - 1.54 & Poor \\
5. & 1.50 - 1.61 & Very poor \\
6. & > 1.67 & Very, very poor \\
\hline
\end{array} \]

\[ \begin{array}{|c|c|c|c|}
\hline
\text{Sr. No.} & \text{Angle of Repose (θ)} & \text{Flowability} \\
\hline
1. & < 25 & Excellent \\
2. & 25 - 30 & Good \\
3. & 30 - 40 & Passable \\
4. & > 40 & Very Poor \\
\hline
\end{array} \]

6) Particle size

Particle size measurement entails shaking the sample with an sieve through a succession of sequentially positioned sieves (Sieve No. 10, 20, 30, 44, 60, 100, and pan), weighing the portion of the sample retained on each sieve, and calculating the result.

D. Evaluation of Post Compression Study: [8],[11],[13]-[15]

1) Appearance

Colour and Shape were physically examined.

2) Hardness

Tablet hardness is the amount of force necessary to break a tablet under a diametric compression force. Monsanto's hardness tester was used to measure it. It’s measured in kilograms per square meter (kg/cm²).

3) Thickness

Screw Gauge was used to determine the thickness of the tablets, which was given in millimeters.

4) Weight Variation

The average weight was calculated after a random selection of 10 tablets. Individual tablets were then weighed, and their weights were compared to a national average.

5) Friability

Friability of tablet was measured using Digital Programmable Friability Apparatus. Initially, 10 tablets were weighed and put in the friability. For 4 minutes, the friability was rotated at 25 rpm. The tablets were weighed once again (W= final weight). After then, the percentage friability was calculated. Friability of less than 1% was deemed acceptable.

\[ \text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100 \] (6)

6) Wetting Time

Wetting time is influenced by the tablet's interior structure as well as the excipient's hydrophilicity. It is known that as compression force or porosity decreases, pores narrow and wetting time increases. In a petri dish holding 6 ml of water, a double-folded piece of tissue paper was inserted. The tablet was placed on the paper, and the time it took to completely moisten the tablet was measured in seconds.

7) Drug Content Uniformity

Twenty tablets were broken to powder with a mortar and pestle to determine drug content. A powder containing 10 mg of medication was taken and dissolved in the correct amount of solvent. The amount of drug within the tablet was analyzed after proper dilution of the test solution by using a UV
spectrophotometer against the reference solution with suitable dilutions at 326 nm for Phosphate Buffer Solution (pH 7.2) respectively.

8) In-Vitro Disintegration Time
At 37 ± 0.5 °C the tablet was placed in a beaker containing 20 mL of distilled water. The time it took for the tablet to completely disintegrate was measured thrice.

9) In-Vitro Dissolution Study
The fast-dissolving tablets were examined in vitro in a USP class II dissolution apparatus (LAB INDIA) with a paddle stirrer at 100 rpm and 900 ml of pH 7.2 phosphate buffer at 37 ± 0.5 °C as a dissolution medium. In each test, one tablet was utilized. At defined time intervals (0, 2, 4, 6, 8, 10, and 15 minutes), aliquots of 5 ml were removed and replaced with an equivalent volume of fresh medium. The drug content of the removed aliquots was determined spectrophotometrically at a wavelength of 326 nm. The drug concentration was determined and reported as a percentage of the total amount of drug discharged. The dissolving experiments were performed three times.

10) Stability Studies
The stability study of the tablets was carried out by keeping the samples within the stability chamber at 40±20 °C/75±5 %RH for 3 months as per the ICH (International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) guidelines. The optimized group was chosen for stability studies. The tablets were assessed for hardness, friability, drug content (Assay), disintegration time, and in vitro drug release profile after a 1-month interval till 3 months.

IV. RESULT AND DISCUSSION
A. Preformulation Studies
1) Organoleptic Properties

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Properties</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Appearance/Nature</td>
<td>Crystalline Powder</td>
</tr>
<tr>
<td>2.</td>
<td>Colour</td>
<td>Yellow</td>
</tr>
</tbody>
</table>

Sulindac was physically examined for organoleptic properties like appearance and was observed to be crystalline powder and yellow coloured.

2) Physicochemical Properties

a) Determination of Solubility

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Solvent</th>
<th>Solubility Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Ethanol</td>
<td>Soluble (2 mg/ml)</td>
</tr>
<tr>
<td>2.</td>
<td>Phosphate Buffer</td>
<td>Very Soluble</td>
</tr>
</tbody>
</table>

Solubility of Sulindac in a solvent like ethanol was found to be soluble (2 mg/ml) and phosphate buffer was found to be very soluble.

b) Melting Point Determination

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Melting point</th>
<th>Avg. melting point</th>
<th>Standard melting point</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>183 °C</td>
<td>183.66 °C</td>
<td>182-185 °C</td>
</tr>
<tr>
<td>2.</td>
<td>184 °C</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The melting point of Sulindac was done in triplicate and the average melting point was found to be 183.66 °C, which is in between standard melting point i.e., 182-185 °C.

3) Spectrophotometric Analysis

a) Determination of λmax of Sulindac in Ethanol

The drug was weighed and dissolved in ethanol to obtain a concentration of 100 ppm. Further, this solution was scanned between 200-400 nm. λmax of sulindac was found to be 326 nm.

- Calibration Curve of Sulindac in Ethanol
From the standard stock solution of sulindac, dilutions of 10, 20, 30, 40 and 50 ppm were prepared and absorbance was measured by using a UV visible double beam spectrophotometer.

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Concentration</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>10</td>
<td>0.378</td>
</tr>
<tr>
<td>2.</td>
<td>20</td>
<td>0.745</td>
</tr>
<tr>
<td>3.</td>
<td>30</td>
<td>1.183</td>
</tr>
<tr>
<td>4.</td>
<td>40</td>
<td>1.546</td>
</tr>
<tr>
<td>5.</td>
<td>50</td>
<td>1.935</td>
</tr>
</tbody>
</table>

Fig. 1. Absorption Spectra of Sulindac in Ethanol.

Calibration curve of sulindac in ethanol at 326 nm and the equation of y was found to be y = 0.0391x - 0.0126 and R2 was found to be 0.999.

b) Determination of λmax of Sulindac in Phosphate Buffer Solution pH 7.2
To obtain a concentration of 100 ppm, the drug was weighed and dissolved in a phosphate buffer solution with a pH of 7.2. To obtain further dilutions, this solution was utilized as a standard stock solution.
The UV scan was performed between the wavelength range of 200-400 nm and the highest peak in the spectra was selected as the maximum wavelength for Sulindac and its found to be 326 nm.

- **Calibration Curve of Sulindac in Phosphate Buffer Solution pH 7.2**

  From the standard stock solution of sulindac, dilutions of 10, 20, 30, 40 and 50 ppm were prepared and the absorbance was measured by using a UV visible double beam spectrophotometer.

  TABLE X: CALIBRATION AND LINEARITY OF SULINDAC IN PBS pH 7.2

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Concentration</th>
<th>Absorbance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>10</td>
<td>0.41</td>
</tr>
<tr>
<td>2.</td>
<td>20</td>
<td>0.744</td>
</tr>
<tr>
<td>3.</td>
<td>30</td>
<td>1.02</td>
</tr>
<tr>
<td>4.</td>
<td>40</td>
<td>1.362</td>
</tr>
<tr>
<td>5.</td>
<td>50</td>
<td>1.758</td>
</tr>
</tbody>
</table>

The calibration curve of sulindac in PBS pH 7.2 at 326 nm and the y equation was found to be \( y = 0.0331x + 0.0646 \) and \( R^2 \) was found to be 0.996.

4) **FTIR Analysis**

a) **FTIR Spectra of Sulindac and Excipients**

- **FTIR Spectra of Sulindac**

  TABLE XI: FUNCTIONAL GROUP AND WAVE NUMBER VALUES OF SULINDAC

<table>
<thead>
<tr>
<th>C=O stretch</th>
<th>1650-1780</th>
<th>1695.43</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-H stretch</td>
<td>2700-3300</td>
<td>2765.92</td>
</tr>
<tr>
<td>Aromatic Ring</td>
<td>1450-1600</td>
<td>1460.11</td>
</tr>
<tr>
<td>C=C stretch</td>
<td>1670-1566</td>
<td>1595.13</td>
</tr>
<tr>
<td>O-H bending</td>
<td>1310-1440</td>
<td>1411.89</td>
</tr>
<tr>
<td>C-F</td>
<td>1145-1155</td>
<td>1147.65</td>
</tr>
</tbody>
</table>

b) **FTIR Spectra of Excipients**

- **FTIR Spectra of Crospovidone**

Fig. 4. Calibration curve of Sulindac in PBS 7.2 at 326 nm.

Fig. 5. FTIR Spectra of Sulindac.

Fig. 6. FTIR Spectrum of Crospovidone.
- Drug-Excipient Compatibility Study

Fig. 7. FTIR Spectrum of Sodium Starch Glycolate.

Fig. 8. FTIR Spectrum of Croscarmellose Sodium.

Fig. 9. FTIR Spectrum of Saccharin.

Fig. 10. FTIR Spectrum of F3 Formulation.
B. Precompression Evaluation

<table>
<thead>
<tr>
<th>For. No.</th>
<th>Particle size (µm)</th>
<th>Bulk density (g/cm³)</th>
<th>Tapped density (g/cm³)</th>
<th>Hausner’s ratio</th>
<th>Carr’s index (%)</th>
<th>Angle of repose (°)</th>
<th>Drug Content (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>237.38 ± 3.58</td>
<td>0.505 ± 0.0036</td>
<td>0.666 ± 0.0083</td>
<td>1.318 ± 0.0126</td>
<td>24.17 ± 0.7749</td>
<td>42.92 ± 6.186</td>
<td>79.22 ± 5.367</td>
</tr>
<tr>
<td>F2</td>
<td>235.72 ± 3.58</td>
<td>0.502 ± 0.0036</td>
<td>0.671 ± 0.0083</td>
<td>1.33 ± 0.0126</td>
<td>25.18 ± 0.7749</td>
<td>46.74 ± 6.186</td>
<td>80.42 ± 5.367</td>
</tr>
<tr>
<td>F3</td>
<td>232.80 ± 3.58</td>
<td>0.5 ± 0.0036</td>
<td>0.666 ± 0.0083</td>
<td>1.332 ± 0.0126</td>
<td>24.9 ± 0.7749</td>
<td>63.71 ± 6.186</td>
<td>81.64 ± 5.367</td>
</tr>
<tr>
<td>F4</td>
<td>236.91 ± 3.58</td>
<td>0.5 ± 0.0036</td>
<td>0.657 ± 0.0083</td>
<td>1.31 ± 0.0126</td>
<td>23.89 ± 0.7749</td>
<td>45.84 ± 6.186</td>
<td>76.12 ± 5.367</td>
</tr>
<tr>
<td>F5</td>
<td>236.96 ± 3.58</td>
<td>0.497 ± 0.0036</td>
<td>0.653 ± 0.0083</td>
<td>1.31 ± 0.0126</td>
<td>23.88 ± 0.7749</td>
<td>46.56 ± 6.186</td>
<td>78.08 ± 5.367</td>
</tr>
<tr>
<td>F6</td>
<td>237.07 ± 3.58</td>
<td>0.495 ± 0.0036</td>
<td>0.657 ± 0.0083</td>
<td>1.32 ± 0.0126</td>
<td>24.65 ± 0.7749</td>
<td>45.14 ± 6.186</td>
<td>79.44 ± 5.367</td>
</tr>
<tr>
<td>F7</td>
<td>238.65 ± 3.58</td>
<td>0.505 ± 0.0036</td>
<td>0.666 ± 0.0083</td>
<td>1.31 ± 0.0126</td>
<td>24.17 ± 0.7749</td>
<td>45.14 ± 6.186</td>
<td>86.12 ± 5.367</td>
</tr>
<tr>
<td>F8</td>
<td>227.95 ± 3.58</td>
<td>0.505 ± 0.0036</td>
<td>0.666 ± 0.0083</td>
<td>1.31 ± 0.0126</td>
<td>24.17 ± 0.7749</td>
<td>45.25 ± 6.186</td>
<td>82.48 ± 5.367</td>
</tr>
<tr>
<td>F9</td>
<td>230.85 ± 3.58</td>
<td>0.5 ± 0.0036</td>
<td>0.645 ± 0.0083</td>
<td>1.29 ± 0.0126</td>
<td>22.48 ± 0.7749</td>
<td>46.36 ± 6.186</td>
<td>94.1 ± 5.367</td>
</tr>
</tbody>
</table>

C. Post Compression Evaluation

<table>
<thead>
<tr>
<th>For. No.</th>
<th>Hardness (kg/cm²)</th>
<th>Thickness (mm)</th>
<th>Weight Variation (% w/w)</th>
<th>Fractureability (sec)</th>
<th>Disintegration (sec)</th>
<th>Wetting Time (sec)</th>
<th>Physical Appearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>4.2</td>
<td>3</td>
<td>0.703</td>
<td>34</td>
<td>25</td>
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</tr>
<tr>
<td>F2</td>
<td>4.1</td>
<td>3</td>
<td>0.721</td>
<td>23</td>
<td>23</td>
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<td></td>
</tr>
<tr>
<td>F3</td>
<td>4</td>
<td>3</td>
<td>0.734</td>
<td>18</td>
<td>20</td>
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<td></td>
</tr>
<tr>
<td>F4</td>
<td>2.5</td>
<td>3</td>
<td>0.728</td>
<td>78</td>
<td>46</td>
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</tr>
<tr>
<td>F5</td>
<td>2.5</td>
<td>3.1</td>
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<td>3</td>
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<tr>
<td>F7</td>
<td>5.1</td>
<td>3.1</td>
<td>0.836</td>
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<td>3.1</td>
<td>0.852</td>
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<tr>
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<td>3</td>
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<td>484</td>
<td>80</td>
<td>Yellow in colour, Round in shape</td>
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</table>

1) In-Vitro Dissolution Study

<table>
<thead>
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<th>Time (min)</th>
<th>F1</th>
<th>F2</th>
<th>F3</th>
<th>F4</th>
<th>F5</th>
<th>F6</th>
<th>F7</th>
<th>F8</th>
<th>F9</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>57.658</td>
<td>83.4</td>
<td>79.79</td>
<td>-3.06</td>
<td>55.85</td>
<td>63.99</td>
<td>0.55</td>
<td>20.86</td>
<td>30.11</td>
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<td>3</td>
<td>4</td>
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<td>93.83</td>
<td>92.74</td>
<td>13.04</td>
<td>82.63</td>
<td>86.64</td>
<td>14.87</td>
<td>45.54</td>
<td>60</td>
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<tr>
<td>4</td>
<td>6</td>
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<td>23.08</td>
<td>90.51</td>
<td>89.84</td>
<td>26.01</td>
<td>58</td>
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<tr>
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<td>8</td>
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<td>90.86</td>
<td>86.3</td>
<td>41.52</td>
<td>92.46</td>
<td>86.35</td>
<td>23.44</td>
<td>64.85</td>
<td>81.06</td>
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<tr>
<td>6</td>
<td>10</td>
<td>91.24</td>
<td>100.96</td>
<td>85.87</td>
<td>40.29</td>
<td>87.17</td>
<td>86.09</td>
<td>46.405</td>
<td>73.19</td>
<td>90.75</td>
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<tr>
<td>7</td>
<td>15</td>
<td>86.48</td>
<td>91.18</td>
<td>93.76</td>
<td>54.66</td>
<td>99.97</td>
<td>86.75</td>
<td>22.73</td>
<td>80.47</td>
<td>91.07</td>
</tr>
</tbody>
</table>
2) Stability Studies

The tablets were tested for stability by storing them in a stability chamber at 40±20 °C/75±5 % RH for three months, as per ICH recommendations. For stability investigations, the optimal group F3 was chosen. After a one-month delay, the tablets were evaluated for hardness, friability, and drug content (Assay) profile.

The Stability Study for Optimized Formulation was evaluated by certain parameters and the optimized formulation was found to be stable within the stability chamber at 40±20 °C/75±5 %RH for 3 months as per the ICH guidelines.

V. CONCLUSION

As per the aim and objectives and plan of work, organoleptic properties of sulindac tablet were seen in yellow crystalline powder, physicochemical properties were seen and the melting point was determined and found to be 183.66 °C. \( \lambda_{\text{max}} \) was found to be at 326 nm in Ethanol and PBS Solution. After that, FTIR studies were done on sulindac, excipients and mixture. Then, precompression studies were performed on the drug and excipients, they were mixed to study its Precompression properties like Bulk density was found to be in the in-between range of 0.495-0.505 g/cc, Tapped density values in the range of 0.653-0.671 g/cc, values of Hausner’s ratio for formulations F1 to F9 was found to be in the range of 1.29-1.332, Carr’s index values for formulations F1 to F9 was found to be in the range of 22.48 to 25.18%, angle of repose was found to be in the range of 42.92- 46.74° and particle size was determined and found to be in the range of 227.95-238.65 µm. Then orodispersible tablet was prepared by direct compression method by using the Kambert compression machine by different super disintegrants of different concentrations such as Croscarmellose sodium, Sodium starch glycolate and Crosspovidone. The Nine different batches of formulations were prepared and evaluated for their various official and nonofficial specifications. The Post compression properties like the Physical Appearance of Sulindac ODTs were round in shape and yellow colored. Hardness for all formulations were found to be between 2.2 to 5.1 kg/cm². Thickness values for all formulations were found to be 3 to 3.1 mm. Friability is below 1% and it's acceptable. Weight variation has also passed the test because all values are in between the lower limit and upper limit. % Drug content were found to be in the range of 76.22 to 94.1% w/w. Disintegration time were found to be in between 18 to 489 secs. wetting time for all formulations were found to be in between 20 to 84 secs and Invitro drug release were performed and in range of 22.73% to 99.97%. The Optimized formulation, F3 was selected and was found to be stable and has good physical appearance and certain parameters evaluated and found to be good and stable under certain conditions for 3 months. So, proposed aim was satisfied. ODTs gain special characteristics that render them a unique dosage form and an easy route of administration with an ultimate clinical output. Many drugs can be formulated as ODTs especially unpalatable drugs and drugs with lowered bioavailabilities. However, research studies are still in progress in order to develop novel ODT pharmaceutical products including more classes of drugs. Owing to the enhanced technological developments, the coming ODTs future trends will bring greatly different disciplines within the pharmaceutical market.

CONFLICT OF INTEREST

Authors declare that they do not have any conflict of interest.
REFERENCES


